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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,119	06/14/2001	Andrew D. Ellington	119927-1050	8203

30623 7590 06/03/2003

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.  
ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

17

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/883,119

Applicant(s)

ELLINGTON ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-136 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-136 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. After further consideration, the examiner has concluded that the election/restriction requirement mailed 10/02/2002 was incomplete because it did not properly set forth the differences between the multiple patentably distinct forms of nucleic acid molecules claimed by Applicant.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, and 128, drawn to a polynucleotide that is regulated by a polypeptide, wherein a peptide interacts with the polynucleotide to affect its catalytic activity, classified in class 536, subclass 24.1.
- II. Claims 15-44, 83-92, and 129 drawn to a nucleic acid that is regulated by an effector, wherein a catalytically active nucleic acid is generated by the modification of one catalytic residue, classified in class 536, subclass 24.1.
- III. Claims 45-52, drawn to a nucleic acid comprising a gene; a regulatable, catalytically active nucleic acid inserted within the gene; wherein the presence of an effector causes the nucleic acid to catalyze a reaction, classified in class 536, subclass 23.1.
- IV. Claims 53-54 drawn to a regulatable catalytically active nucleic acid in which one or more catalytic residues has been randomized, classified in class 536, subclass 24.1.
- V. Claims 55-81, and 93-127, drawn to methods of isolating a regulatable catalytically active nucleic acid molecule, classified in class 435, subclass 6.

VI. Claim 82 and 130-136, drawn to a method of modifying a target or a method of modulating expression of a nucleic acid, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecules of inventions I-IV and the biosensor of invention V, can be used in a method for isolating effectors which interact with or regulate the catalytic activity of said catalytically active nucleic acid molecules.

4. Inventions I-IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acid molecules of inventions I-IV can be isolated by standard chemical synthetic methods commonly known in the art, wherein a specific catalytically active nucleic acid (for example a ribozyme or DNAzyme, the structures of which are well known in the art), having a specifically designed structure, is synthetically made by standard procedures.

5. The methods of inventions V and VI are drawn to patentably distinct methods, comprising distinct method objectives, steps, reactants, and outcomes.

6. The nucleic acid molecules of inventions I-IV have patentably distinct structures and possess distinct modes of operation. For example, the nucleic acid molecule of invention I is

Art Unit: 1635

regulated by peptide interaction, however the nucleic acid of invention II is regulated by modification of at least one catalytic residue by an effector (assuming this is the correct interpretation of claims 15-44 and 129). The nucleic acid molecule of invention III comprises a gene with a catalytically active nucleic acid inserted within the gene, and regulated by an effector. The nucleic acid molecules of inventions I-II and IV are not disclosed as comprising a gene. The nucleic acid molecules of invention IV comprise at least one randomized catalytic residue, inventions I-III are not disclosed as comprising randomized residues.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and Groups I-IV would require a separate search of the prior art, and the search required for Group V is not required for Group VI, restriction for examination purposes as indicated is proper.

9. A telephone call was made to Ivor Elrifi on 6-02-03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

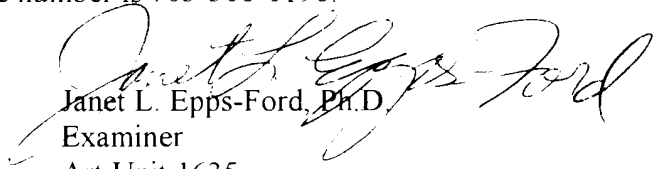
Art Unit: 1635

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fr, 8:30AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

JLE  
June 2, 2003